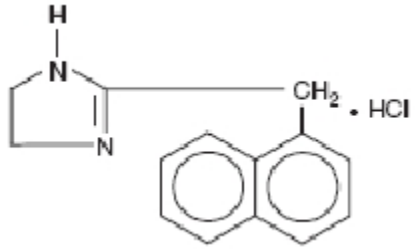
NAPHAZOLINE HYDROCHLORIDE - naphazoline hydrochloride solution/ drops
Bausch & Lomb Incorporated

DESCRIPTION

Naphazoline Hydrochloride Ophthalmic Solution USP, 0.1%, a sterile solution, is an ocular vasoconstrictor and imidazoline derivative sympathomimetic amine. It occurs as a white, odorless, crystalline powder having a bitter taste and is freely soluble in water and in alcohol. The active ingredient is represented by the following structural formula:



$C_{14}H_{14}N_2 \cdot HCl$

Mol. Wt. 246.74

Chemical Name: 2-(1-naphthylmethyl)-2-imidazoline monohydrochloride
Each mL Contains: ACTIVE: Naphazoline Hydrochloride, 1 mg (0.1%); INACTIVES: Boric Acid, Sodium Chloride, Edetate Disodium, Sodium Carbonate, Purified Water. Sodium Carbonate and/or Hydrochloric Acid may be added to adjust pH (5.5 - 7.0). PRESERVATIVE ADDED: Benzalkonium Chloride 0.01%.

CLINICAL PHARMACOLOGY

Naphazoline constricts the vascular system of the conjunctiva. It is presumed that this effect is due to direct stimulation action of the drug upon the alpha adrenergic receptors in the arterioles of the conjunctiva resulting in decreased conjunctival congestion. Naphazoline belongs to the imidazoline class of sympathomimetics.

INDICATIONS AND USAGE

Naphazoline Hydrochloride Ophthalmic Solution is indicated for use as a topical ocular vasoconstrictor.

CONTRAINDICATIONS

Contraindicated in the presence of an anatomically narrow angle or in narrow angle glaucoma or in persons who have shown hypersensitivity to any component of this preparation.

WARNINGS

NOT FOR INJECTION INTO THE EYE - FOR TOPICAL USE ONLY.
Patients under therapy with MAO inhibitors may experience a severe hypertensive crisis if given a sympathomimetic drug. Use in pediatric patients, especially infants, may result in CNS depression leading to coma and marked reduction in body temperature.

PRECAUTIONS

General

Use with caution in the presence of hypertension, cardiovascular abnormalities, hyperglycemia (diabetes), hyperthyroidism, infection or injury.

Information for patients

Patients should be advised to discontinue the drug and consult a physician if relief is not obtained within 48 hours of therapy, if irritation, blurring or redness persists or increases, or if symptoms of systemic absorption occur, i.e., dizziness, headache, nausea, decrease in body temperature, or drowsiness.
To prevent contaminating the dropper tip and solution, do not touch the eyelids or the surrounding area with the dropper tip of the bottle. If solution changes color or becomes cloudy, do not use.

Drug Interactions

Concurrent use of maprotiline or tricyclic antidepressants and naphazoline may potentiate the pressor effect of naphazoline.
Patients under therapy with MAO inhibitors may experience a severe hypertensive crisis if given a sympathomimetic drug. (See WARNINGS).

Pregnancy

Category C
Animal reproduction studies have not been conducted with naphazoline. It is also not known whether naphazoline can cause fetal harm when administered to a pregnant woman or can effect reproduction capacity. Naphazoline should be given to a pregnant woman only if clearly needed.

Nursing mothers
It is not known whether naphazoline is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when naphazoline is administered to a nursing woman.

Pediatric use
Safety and effectiveness in pediatric patients have not been established. See "WARNINGS" and "CONTRAINDICATIONS".

ADVERSE REACTIONS
Ocular: Mydriasis, increased redness, irritation, discomfort, blurring, punctate keratitis, lacrimation, increased intraocular pressure.
Systemic: Dizziness, headache, nausea, sweating, nervousness, drowsiness, weakness, hypertension, cardiac irregularities, and hyperglycemia.

DOSAGE AND ADMINISTRATION
Instill one or two drops into the conjunctival sac(s) every three to four hours as needed.

HOW SUPPLIED
Naphazoline Hydrochloride Ophthalmic Solution USP, 0.1%, is available in a plastic squeeze bottle with controlled drop tip in the following size:
15 mL bottle - Prod. No. 04611
STERILE OPHTHALMIC SOLUTION
Rx only
FOR OPHTHALMIC USE ONLY.

STORAGE CONDITIONS
Store between 15°- 30°C (59°-86°F).
DO NOT USE IF IMPRINTED NECKBAND IS NOT INTACT.
KEEP OUT OF REACH OF CHILDREN.

MANUFACTURING INFORMATION
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